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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,251	11/01/2001	Robert K. Naviaux	UCSD1140-1	9760

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/889,251	NAVIAUX, ROBERT K.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67,74-81,84-91,95-111 and 114-145* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *95-110 and 130-144* is/are allowed.

6)☒ Claim(s) *67,74-81,84-91,111, 114-129, 145* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Amendment filed August 7, 2008 is acknowledged. Claims 1-66, 68-73, 82, 83, 92-94, 112,113 and 146-180 are, or previously were, canceled. Claims 67, 74-81, 84-91, 95-111 and 114-145 remain under consideration.

The rejection set forth in the last Office Action under 35 U.S.C. 112, second paragraph, is withdrawn. The following rejections are the only rejections presently applied to the instant claims.

Claims 67, 74-81, 84-91, 111 and 114-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The limitation "with further proviso that the mitochondrial disorder is selected from the group consisting of: a primary disorder caused by at least one mutation in mitochondrial or nuclear DNA; and a secondary disorder caused by acquired somatic mutations, physiologic effects of drugs, viruses or environmental toxins that inhibit mitochondrial function" does not find clear antecedent basis in the specification as filed. Accordingly, the limitation added to instant claims 67, 91, 111 and 129 introduces new matter. See *In re Rasmussen*, 211 USPQ 323 (CCPA 1981).

In the last Office Action claims 67, 70, 73-81, 84-91, 96-109 and 111-179 remained rejected under 35 U.S.C. 103 as being obvious over Nagley et al., U.S. Patent 5,981,601, in view of Page et al., Proc. National Academy of Sciences. It was asserted Nagley teaches the administration of uridine, including functional derivatives and/or

precursors thereof, to treat mitochondrial disorders wherein at least one mutation in the mitochondria has occurred. Primarily, Nagley's teaching is drawn to the mitochondrial toxicity and physiologic effects that result from the administration of the reverse transcriptase inhibitor drug AZT. See claims 1, 5, 6, 10 and 18, column 18-20 and 24. AZT acts as a mitochondrial poison in that it causes cellular cytotoxicity, which is particularly manifest in muscle, causing myopathy. As a mitochondrial poison, AZT disrupts mitochondrial respiratory chain function resulting in a reduced capacity for generating ATP. Specifically, AZT affects the oxidation/phosphorylation system and the activity of complex I and IV of the mitochondrial respiratory chain. As required by instant claims 85, 86, 104 and 105, the administration of uridine may be accompanied by the administration of one or more co-factors or vitamins, such as coenzyme Q or an antioxidant as ascorbic acid. See Example 1, column 11. See column 5, lines 50-55, where Nagley's claimed redox compounds may include vitamins of the K series or ascorbic acid. See column 3, lines 50-60. Anti-oxidant scavengers include α-lipoic acid, as recited in instant claims 87 and 106. Further, other diseases associated with disruption of the mitochondrial respiratory chain function are also included in Nagley's teaching. See column 8, line 63, to column 9, line 10, where encephalomyopathy lactic acidosis is included among those mitochondrial pathologies contemplated. As required by instant claims 88, 89, 107 and 108, see column 7, lines 3-5, where the disclosed daily dosage range overlaps with those instantly claimed. The claimed recitation "about 2 gm/m^2 overlaps with Nagley's teaching of 2000 mg per day.

Applicant argues even though a broad latitude in reading claims is allowed, the claims have been read too broadly in that the current disclosure has nothing to do with AZT or other kinds of therapeutics. Applicant urges further that amended claims 67, 91, 111 and 129 now recite the closed language "consisted of."

In fact, independent claims 67, 91 and 95 still recite the closed language "comprising."

In response to Applicant's assertion drawn to too broad an interpretation, a reference may be applied not only for what it expressly teaches by direct anticipation, but also for what one of ordinary skill in the art might reasonably infer from the teachings. See *In re Opprecht*, 12 USPQ 2d, 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976).

In light of the foregoing, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a). The rejection of record under 35 U.S.C. 103 is maintained over claims 67, 74-81 and 84-91 for the reasons of record. AZT is a mitochondrial poison, a reverse transcriptase inhibitor and a pharmaceutical agent that is encompassed in the claimed subject matter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 8, 2008 /Phyllis G. Spivack/

Primary Examiner, Art Unit 1614